

## **REMARKS**

Applicants have carefully examined the Office Action of December 2, 2008, in which claims 74, 77-84, 87-91, 130-133 and 140-153 are pending in the application and have been rejected. Applicants respectfully request re-examination in light of the above amendments and following remarks.

### **Objections**

Claims 150 and 152 were objected to as reciting “as” rather than “has.” Applicants have corrected this typographical error and thank the Examiner for catching this error.

### **35 USC 103 Rejections**

Claims 74, 77-79, 84, 87-88, 130, 132, 140, 142, 144-150 and 152 were rejected under 35 USC 103(a) as being unpatentable over Callol, USPN 6,709,440. Applicants respectfully traverse the rejection.

The Office Action notes that “Callol et al. fails to explicitly teach that the tensile strength of the polyamide is at least about 21,000 psi, and the recited thickness of the wall shaft” and that Callol teaches that the polyamide of the shaft has a tensile strength of at least 15,000 psi. Page 5. Callol apparently does not recite any wall thickness dimensions.

In the Response to Arguments section, the Examiner’s states that applicants do not acknowledge or address the argument that varying the thickness of the wall shaft in order to achieve the desired degree of strength would have been obvious, since “discovering an optimum value of a results effective variable involves only routine skill in the art in the absence of unexpected results.” The Examiner goes on to write that “Callol et al. confirms that an increase in thickness of a polymeric material increases its strength (and vice versa)” as well as its radial strength.

There thus seems to be some confusion about the terms “tensile strength” and “hoop stress.” Tensile strength is a term of art. Tensile strength does not indicate how much load a particular specimen can bear; it is an intensive property that is independent of the values of the particular specimen. It is expressed in terms of force per unit area (which indicates that it

is a property independent of the size of the specimen). A piece of steel an inch in diameter can bear a certain load; a piece of steel two inches in diameter can bear a greater load. Both have the same tensile strength. See [http://en.wikipedia.org/wiki/Tensile\\_strength](http://en.wikipedia.org/wiki/Tensile_strength). Thus one cannot vary the thickness of the shaft to achieve a different tensile strength.

Callol teaches “a tensile strength of at least 15,000 psi.” Read from one perspective, the range taught is from 15,000 psi to infinity, because this is an open-ended phrase. However, this cannot be. Applicants gave as an example that a material with a tensile strength of at least 50,000,000 psi is not enabled because such a tensile strength is above the theoretical top limit for tensile strength and is far above any measured tensile strength. Thus the perspective that Callol teaches any tensile strength greater than 15,000 psi is clearly incorrect. There is nothing to suggest a different top limit for the enabled tensile strengths taught by Callol, and applicants know of no principle by which one could say that Callol teaches materials with tensile strengths of, say, between 15,000 psi and 30,000 psi. The disclosure does not appear to be there. Thus, while 21,000 psi is much closer to 15,000 psi than to 50,000,000 psi, there is nothing in Callol to suggest that 21,000 psi is enabled by the disclosure of Callol. It is simply not possible to enable an indefinite range through the use of open-ended language.

Further, both independent claims recites “a wall thickness of about 0.001 inch to about 0.04 inch.” Thus one cannot vary the wall thickness beyond 0.04 inch to achieve a desired tensile strength or hoop stress and read on the claim language. There is nothing in Callol to suggest that one can vary properties such as wall thickness, tensile strength or hoop stress and achieve the balloon catheter as claimed in claim 74 or 84. Creating a catheter shaft with desired properties is not routine; there is no certain procedure an experimenter can follow to obtain desired results. As applicants say in paragraph 121 of the application as published:

Without wishing to be bound by theory, it is believed that the longitudinal and radial stretch-blown processes described herein can result in a relatively strong tube-shaped catheter component. In particular, it is believed that the use of a longitudinal strain and/or pressure during the stretch-blowing portion of the process ultimately results in a tube-shaped catheter component that is relatively thin, but that has, for example, a burst pressure and/or load at break

that is comparable to those achieved by tube-shaped catheter component preparation processes that result in relatively thick tube-shaped catheter components (e.g., processes in which a longitudinal strain and/or pressure is not used). It is believed that longitudinal and radial stretch-blowing result in relatively thin tube-shaped catheter components that have relatively large tensile strengths and/or relatively large hoop stresses.

This radial stretch blowing process is the process used to achieve the balloon catheters as claimed. This is not a conventional manufacturing process; most catheter shafts are merely extruded, and Callol does not suggest that one can achieve the claimed results through conventional techniques.

Because the tensile strength of a polyamide cannot be varied as desired through routine experimentation, “a polyamide having a tensile strength of at least about 21,000 psi” as recited in claim 74 is not obvious over Callol, which teaches only a polyamide with a tensile strength of greater than 15,000 psi. Applicants according submit that this claim is in condition for allowance. As claims 77-79, 130, 140 and 144-150 depend therefrom and contain additional elements, applicants submit that these claims are also in condition for allowance.

Claim 84 recites “a polyamide having a hoop stress of at least about 3300 psi.” For reasons similar to those discussed above with respect to claim 74, applicants submit that this claim is also non-obvious over Callol. The creation of a polyamide with the recited property involves more than routine experimentation as the hoop stress is not a variable that can be easily altered; it is a property whose discovery involves more than routine experimentation. Applicants therefore submit that claim 84 is in condition for allowance. As claims 87-88, 132, 142 and 152 depend from claim 84 and contain additional elements, applicants submit that these claims are also in condition for allowance.

### **Conclusion**

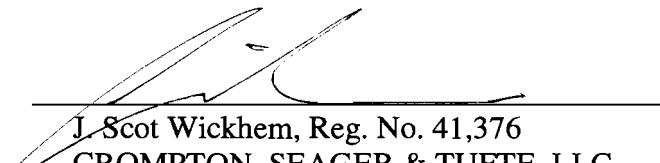
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that the claims are now in condition for allowance, issuance of a Notice of

Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,  
VICTOR SCHOENLE et al.

By their Attorney,

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J. Scot Wickhem, Reg. No. 41,376  
CROMPTON, SEAGER & TUFTE, LLC  
1221 Nicollet Avenue, Suite 800  
Minneapolis, Minnesota 55403-2420  
Telephone: (612) 677-9050  
Facsimile: (612) 359-9349